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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,580	01/24/2005	Luc De Vuyst	DECLE69.003APC	9933
20995 7590 10/01/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT 1651	PAPER NUMBER
			NOTIFICATION DATE 10/01/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Office Action Summary**

Application No.

10/516,580

Applicant(s)

DE VUYST ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 6-18, 22-31, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 19-21 and 32-35 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-27-04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed June 11, 2007, has been received and entered.

Claims 1-37 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-5, 19-21, and 32-35, drawn to *Streptococcus thermophilus* ST 111 and a method of using a culture of the strain for fermentation, in the reply filed on June 11, 2007, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 6-18, 22-31, 36, and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1-5, 19-21, and 32-35 are examined on the merits to the extent they read on the elected subject matter.

#### ***Claim Objections***

Claims 2 and 3 are objected to because of the following informalities: Both recite "an exopolysaccharide-producing lactic acid bacterial strain of Claim 1," wherein "an" should be replaced with "the." Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 19-21, and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the microorganism *Streptococcus thermophilus* ST 111 (LMG P-21524) is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. Moreover, because no taxonomic information appears in the specification, it is not clear what the microorganism actually is.

However, since a deposit has been made under the terms of the Budapest Treaty (as stated on pages 38-41 of the specification as filed); then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably

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removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 19-21, and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since the claim recites a strain "...encoding exopolysaccharide production." It is unclear how a strain can encode exopolysaccharide production since only genetic material can accomplish this. Thus, claims 1-5, 19-21, and 32-35 are rejected under 35 U.S.C. 112, second paragraph.

Claims 4 and 32 are rendered indefinite by the recitation " $2 \cdot 10^6$  Dalton." The recitation " $2 \cdot 10^6$  Dalton" is improper scientific notation, and for examination purposes, will be read as " $2 \cdot 10^6$  Dalton."

Claim 19 is rendered indefinite by the recitation "...adding the *Streptococcus thermophilus* ST 111 strain according to claim 1 to the food fermentation process." It is unclear how the strain is added to the food fermentation process, and there is no indication of where in the steps of the process the addition of the strain takes place.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, and 19-21 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lemoine et al. (US 5,965,127) or Faber et al. (Carbohydrate Research. 1998. 310: 269-276, listed on IDS).

Lemoine et al. discloses an exopolysaccharide originating from *Streptococcus thermophilus* (column 2, lines 18-22) which was eluted at the exclusion limit of approximately  $2 \times 10^6$  Dalton (column 4, lines 20-30), thus having a molecular weight of approximately  $2 \times 10^6$  Dalton. The exopolysaccharide comprises various monosaccharides (column 2, lines 18-22) and is therefore considered a heteropolysaccharide. The exopolysaccharide is prepared by fermentation of a growth medium comprising skim milk powder by a strain of *Streptococcus thermophilus* (column 3, lines 55-67). This fermentation could be considered the fermentation of a milk product (food product). Furthermore, Lemoine et al. teaches a food composition comprising a live bacteria producing or having produced in-situ the exopolysaccharide (column

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3, lines 34-38). Example 3 describes the inoculation of whey milk with a culture of *S. thermophilus* (column 7, line 60 through column 8, line 24). Clearly, Lemoine et al teaches an *S. thermophilus* strain which produces a heteropolysaccharide having a molecular weight of at least  $2 \times 10^6$  Dalton, as well as a functional starter culture used in a dairy food fermentation process which yields the heteropolysaccharide.

Faber et al. discloses a milk culture of strains of *S. thermophilus* which produce exopolysaccharides with an average molecular mass of  $2.6 \times 10^3$  kDa ( $2.6 \times 10^6$  Da) or  $3.7 \times 10^3$  kDa ( $3.7 \times 10^6$  Da) (abstract). The exopolysaccharides are heteropolysaccharides (page 273, second column, second full paragraph). It is noted that milk cultures are inoculated with the strains of *S. thermophilus* (page 274, first column, second-to-last paragraph). It is noted that microbial exopolysaccharides are useful as food thickeners (page 269, second column) and that *S. thermophilus* strains are used in combination with *L. delbruckii* subsp. *bulgaricus* strains as commercial yoghurt starters (page 270, first column, first full paragraph). In sum, Faber et al. teaches an *S. thermophilus* strain which produces a heteropolysaccharide having a molecular weight of at least  $2 \times 10^6$  Dalton, as well as a functional starter culture used in a dairy food fermentation process which yields the heteropolysaccharide.

Though Lemoine et al. and Faber et al. do not specify that any one of the *S. thermophilus* strains disclosed is the *S. thermophilus* ST 111 strain deposited under the accession number LMG P-21524, the *S. thermophilus* strains disclosed in Lemoine et al. and Faber et al. appear to be identical to the presently claimed strain, based on the fact that the prior art strain is a member of the same species and that the prior art strain produces a heteropolysaccharide having a

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molecular weight of at least  $2 \times 10^6$  Dalton. Consequently, the claimed strain appears to be anticipated by the reference.

However, even if the Lemoine and Faber strains and the claimed strain are not one and the same and there is, in fact, no anticipation, the Lemoine and Faber strains would, nevertheless, have rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the references disclose members of the same species as that claimed known to synthesize a heteropolysaccharide having a molecular weight of at least  $2 \times 10^6$  Dalton as that recited in the claims. Thus, the claimed invention as a whole was clearly prima facie obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later



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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 19-21, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemoine et al. or Faber et al. in view of Cravero (US 6,033,691).

As discussed above, Lemoine et al. and Faber et al. anticipate or render obvious claims 1, 2, 4, 5, and 19-21. However, Lemoine et al. and Faber et al. do not expressly disclose a co-culture comprising the exopolysaccharide-producing strain.

Cravero discloses a preparation of a biologically active milk product wherein *Lactobacillus casei*, *Lactobacillus acidophilus*, and *Streptococcus thermophilus* are cultured together with a milk product to arrive at a fermented milk product (claim 1).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used a co-culture of *Streptococcus thermophilus* in preparing a fermented milk product as disclosed in Lemoine et al. and Faber et al. Both Lemoine et al. and Faber et al. teach preparation of a fermented milk product by inoculation with *S. thermophilus*, and since Cravero discloses that a co-culture comprising *S. thermophilus* is suitable for obtaining such a product, there would have been a reasonable expectation of success in using a co-culture comprising *S. thermophilus* in the fermentation processes described in Lemoine et al. and Faber et al. Such a modification would have arrived at the predictable result of obtaining a fermented milk product.

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Further still, it would have been obvious to have inoculated any milk product, including those recited in claims 21 and 35, since the substitution of one milk product for another would have yielded the predictable result of obtaining a fermented milk product.

A holding of obviousness is clearly required.

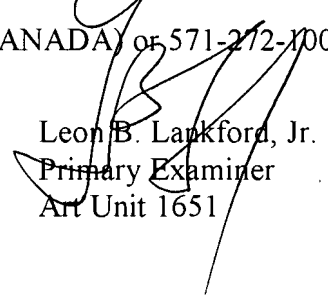
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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